

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

SEP 19 2002

MEMORANDUM

**SUBJECT:** Science Review in Support of the Registration UICK II (EPA Reg. No. 4822-509), Containing 10% p-Menthane-3, 8-Diol (Chemical No. 011550) As Its Active Ingredient. Review of Product Performance (Efficacy) Studies. DP Barcode D282915; Case No. 062676; Submission No. S609621; MRID No. 455642-01.

**FROM:** Russell S. Jones, Ph.D., Biologist  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511C)

**TO:** James Downing, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511C)

**ACTION REQUESTED**

In response to a 3/31/2000 Notice of Registration of UICK II (aka OFF! Botanicals; EPA Reg. No. 4822-509), and a request for additional efficacy studies (see Memorandum from R. S. Jones to J. Downing, dated 6/29/1999), S. C. Johnson submitted additional product performance (efficacy) studies for black flies and biting gnats (MRID 455642-01) in fulfillment of the requirements expressed in a conditional registration.

**RECOMMENDATIONS AND CONCLUSIONS**

The submitted product performance (efficacy) studies for black flies and gnats (no-see-ums) are acceptable and support product label claims of a 2-hour protection time. No additional data are required for black flies and gnats.

**STUDY SUMMARIES**

Product Performance (Efficacy)

Field tests were conducted with human subjects to determine the efficacy of UICK-2 (10% p-menthane-3,8-diol) Formula 15045R59-2 to repel black flies and biting gnats (MRID 455642-01). The biting gnat test was conducted in Crystal River, Florida, and the black fly test was

conducted at Algonquin Provincial Park, Ontario, Canada. Prior to the tests, the forearms and legs of the test subjects were washed with Ivory soap and water, rinsed with an alcohol/water solution, and dried. The product was evenly applied at a rate of 1 g/645 cm<sup>2</sup> to the forearms and lower legs. Protection time was calculated both by the traditional method (first bite followed by a confirming bite within 30 minutes) and by determining the time to <95% repellency. The mean protection time until first confirmed bite was >240 minutes for black flies and 201 minutes for gnats. The time to first bite below 95% repellency was >240 minutes for black flies and 199 minutes for gnats. These protection times exceed the 2-hour protection time claimed on the label.

Classification: Acceptable; no additional data are required for black flies and biting gnats.

cc: R. S. Jones, J. Downing, BPPD Subject File  
R. S. Jones: F.T. CM2, (703) 308-5071: 09/13/2002

# DATA EVALUATION RECORD

## P-MENTHANE-3,8-DIOL (UICK-2)

**STUDY TYPE: Product Performance, OPPTS 810.3300**  
**MRID 45564201**

Prepared for

Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
1921 Jefferson Davis Highway  
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Prepared by

Toxicology and Hazard Assessment Group  
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Assignment No. 132

Primary Reviewer:  
Eric B. Lewis, M.S.

Signature: Eric B. Lewis  
Date: JUL 28 2002

Secondary Reviewers:  
Patricia S. Reno, M.S.

Signature: Patricia S. Reno  
Date: JUL 28 2002

Robert H. Ross, M.S., Group Leader

Signature: Robert H. Ross  
Date: JUL 28 2002

Quality Assurance:  
Lee Ann Wilson, M.A.

Signature: L. A. Wilson  
Date: JUL 28 2002

### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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## DATA EVALUATION RECORD

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**EPA Secondary Reviewer: Russell S. Jones, Ph.D., Biologist**

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<b>STUDY TYPE:</b>	Product Performance, OPPTS 810.3300
<b>MRID NO:</b>	45564201
<b>TEST MATERIAL:</b>	UICK-2 (10% p-menthane-3,8-diol) Formula 15045R59-2
<b>STUDY NO:</b>	377E2
<b>SPONSOR:</b>	S.C. Johnson & Son, Inc.
<b>TESTING FACILITY:</b>	Entomology Research Center, Racine, WI
<b>TITLE OF REPORT:</b>	Determining Repellency of Uick-2 (10% p-methane-3,8-diol) Against Biting Gnats (commonly called no-see-ums) ( <i>Culicoides</i> spp.), and Biting Flies (Black Flies) ( <i>Simulium</i> spp.) in the Field
<b>AUTHOR:</b>	Ropiak, D.T.
<b>STUDY COMPLETED:</b>	November, 2001
<b>CONFIDENTIALITY CLAIMS:</b>	None
<b>STUDY SUMMARY:</b>	Field tests were conducted with human subjects to determine the efficacy of Uick-2 (10% p-menthane-3,8-diol) Formula 15045R59-2 to repel black flies and biting gnats. The mean protection time until first confirmed bite was >240 minutes for black flies and 201 minutes for gnats. The time to first bite below 95% repellency was >240 minutes for black flies and 199 minutes for gnats. These protection times exceed the 2-hour protection time claimed on the label.
<b>CLASSIFICATION:</b>	Acceptable
<b>GOOD LABORATORY PRACTICE</b>	Not GLP compliant, since the study director conducted the testing under the protocol for a previous study, with an amendment that addressed the additional testing. No quality assurance inspections were conducted during the field testing, but the data and final report were audited.

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**TEST MATERIAL:** Uick-2 (10% p-menthane-3,8-diol), Formula No. 15045R59-2

**TEST METHOD:** Field tests using human subjects were conducted to determine the efficacy of Uick-2 (10% p-menthane-3,8-diol) Formula 15045R59-2 against biting gnats (*Culicoides mississippiensis*) and black flies (*Simulium venustum*). The biting gnat test was conducted in Crystal River, Florida, and the black fly test was conducted at Algonquin Provincial Park, Ontario, Canada. Prior to the tests, the forearms and legs of the test subjects were washed with Ivory soap and water, rinsed with an alcohol/water solution, and dried. Using two fingers, Uick-2 was then evenly applied at a rate of 1 g/645 cm<sup>2</sup> to the forearms and lower legs. One of the four limbs of each individual was left untreated to serve as a control. Control limbs were exposed for a 5-minute period (except for one instance when the control exposure was for only one minute due to a high gnat population) at the beginning of each hour and the number of landings was counted. The 5-minute counts were extrapolated to 1-hour counts, and a running control average landing rate was determined throughout the test (an example calculation was provided on p. 8 of the study report). The treated limbs were continuously exposed during the test period and the time of each landing and bite was recorded. Protection time was calculated both by the traditional method (first bite followed by a confirming bite within 30 minutes) and by determining the time to <95% repellency. A treated limb was withdrawn from the test when it received two bites within 30 minutes, or when the percent repellency fell below 95%. The percent repellency was calculated as  $1 - (\text{total number of bites on the treated limb} / \text{average number of bites on the control limb}) \times 100$ .

**RESULTS SUMMARY:** In the black fly test, none of test subjects received a bite during the 240 minute test period, giving an average time to first confirmed bite of >240 minutes and an average time to <95% repellency of >240 minutes. The single limb control landing rate averaged 24-63 landings/hour for the five subjects over the four-hour test.

In the biting gnat test, the time until first confirmed bite ranged from 105 to >290 minutes, with an average of 201 minutes (Table 1). The time to <95% repellency ranged from 132 to >290 minutes, with an average of 199 minutes. The single limb control landing rate averaged 48-312 landings/hour for the three subjects remaining in the test at four hours.

**STUDY AUTHOR'S CONCLUSIONS:** The study author concluded that for biting gnats, Uick-2 provided a mean protection time of 199 minutes using the 95% repellency method, and a mean protection time of 177 minutes using the first confirmed bite method (Table 2). For blackflies, Uick-2 provided a mean protection time of >240 minutes using either method.

**REVIEWER'S CONCLUSIONS:** The study author noted that the protection times presented include those for some subjects who remained in the testing area for longer than 240 minutes, which was the scheduled end of the test. However, the reviewer found that calculating the protection times using a maximum time of 240 minutes did not significantly lower the mean protection times calculated in the study. These protection times exceed the protection time claimed on the draft product label, which is "up to two hours" for both black flies and biting gnats. Based on the data submitted, the reviewer agrees that the product will meet this claim.

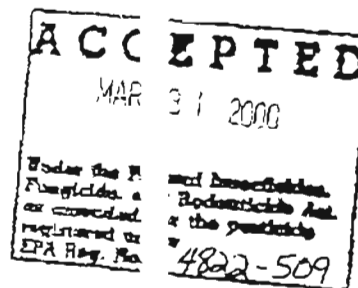
TABLE 1. Uick-2 protection time against biting gnats by test subject				
Subject	Test limb	Time to first bite (min)	Time to first confirmed bite (min)	Time to below 95% repellency (min)
DAS	L. arm	181	181	181
DAS	R. arm	144	249	144
DAS	L. leg	235	235	251
KAC	L. arm	200	245	255
KAC	R. arm	173	219	173
KAC	R. leg	130	130	130
REV	R. arm	195	195	217
REV	L. leg	192	192	193
REV	R. leg	172	224	172
EBW	L. arm	195	234	241
EBW	L. leg	187	187	235
EBW	R. leg	239	290+	290+
DTR	L. arm	155	184	197
DTR	L. leg	148	148	168
DTR	R. leg	105	105	132

TABLE 2. Mean protection time provided by UICK-2 against biting insects in the field				
Reps	Insect	Protection time to first bite (min)	Protection time to first confirmed bite (min)	Time to below 95% repellency (min)
15	Crystal River, FL sand gnats	177	201	199
15	Canadian black flies	240+	240+	240+

## FRONT PANEL

S. C. Johnson (Wax)  
A Family Company

OFF! Botanicals



- NEW
- (Moisturizes) with Aloe (Vera)
- Botanical
- Plant-Based (repellent)
- Feels great on. Keeps bugs OFF!
- Contains Aloe (Vera)
- Protection from annoying mosquitoes (biting flies, gnats and no-see-ums) (for up to two hours)
- Unscented Spritz (Spray)
- Contains eucalyptus extract
- Derived from eucalyptus
- Provides protection from mosquitoes, biting flies, gnats and no-see-ums
- Outdoor Protection
- Contains a botanically-derived insect repellent
- Insect Repellent
- New eucalyptus extract repels Mosquitoes, Biting Flies, Gnats and No-See-Ums
- Repels Mosquitoes, Biting Flies, Gnats and No-See-Ums
- Clean fresh scent
- Light, pleasant scent
- Contains plant extracts (oils, derivatives)
- Non-greasy
- (Insect Repellent) for the entire family
- Not sticky or greasy
- Repels Mosquitoes, Biting Flies, Gnats and No-See-Ums up to 2 hours
- Leaves your skin feeling smooth and natural
- Protects your entire family from annoying mosquitoes (biting flies, gnats and no-see-ums) (for up to two hours)

KEEP OUT OF REACH OF CHILDREN

### WARNING

See back panel for additional precautionary statements and complete directions for use.

### ACTIVE INGREDIENT:

Eucalypta™ (p-Menthane-3,8-diol)\* 10.0%

OTHER INGREDIENTS 90.0%

\* Trademark of S. C. Johnson & Son, Inc.

† cis & trans isomer ratio: min. 50% (+/-) cis and max. 40% (+/-) trans

Net Weight: 4 through 12-fl. oz.



## BACK PANEL

OFF! Botanicals 1's unique formula uses (botanically derived) (plant) oils to repel mosquitoes (biting flies, gnats and no-see-ums). You can feel good about putting it on you and your family. OFF! Botanicals 1 is effective dependable protection that feels great on -- not sticky or greasy -- and it has a light, clean fragrance.

And because it's from the makers of OFF!, it's specially formulated to effectively repel mosquitoes, biting flies, gnats and no-see-ums for up to 2 hours.

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS

#### WARNING

**Causes substantial but temporary eye injury. Do not get in eyes. Do not apply on the face or hands of small children. Do not allow children to apply this product to themselves. Do not apply to excessively sunburned or damaged skin. For external use only. Wash hands thoroughly with soap and water after applying.**

#### FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses if present after the first 5 minutes, then continue rinsing. Get medical attention. **IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor.

### PHYSICAL & CHEMICAL HAZARDS

**Flammable.** Keep away from heat and open flame. Keep treated skin and clothing away from fire, sparks or flame until dry.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. **Read all directions before using this product.**

**General Instructions:** Hold container 6 to 8 inches from skin or clothing and spray with a slow sweeping motion. Do not use as a space spray. Use sufficient repellent to cover exposed skin evenly and completely. For continued protection from biting insects, reapply every two hours or after swimming, perspiration, vigorous activity or to eling. **Application To Face:** Do not spray directly on or near face. Instead, spray in hand and spread on face and neck. Do not apply to face or hands of small children. **Works** For maximum protection, spread evenly with hand to moisten all exposed skin. **On Clothing Too:** Spray shirts, pants, socks and hats. Wash treated clothing before reuse. Do not apply under clothing.